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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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16

DATE MAILED: 8/5/74

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No
09/004,395

Applicant's

GILMORE ET AL

Examiner
N. M. Minnifield

Group Art Unit
1645



X Responsive to communication(s) filed on Mar 6, 2000

X This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11, 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- X Claim(s) 14-17 and 19-21 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- X Claim(s) 14-17 and 19-21 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in full (For No. series (code) Serial Number) _____

received in this application from the International Bureau (PCI Rule 17.2) a

*Certified copies not received _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited (PTO-892)

X Information Disclosure Statement (P.T.O. 1449) Paper No(s) 11, 13, 14

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DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed March 6, 2000 is acknowledged and has been entered. Claim 18 has been canceled. Claims 14-17 have been amended. New claims 19-30 have been added. Claims 14-17 and 19-30 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment and comments, with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 14-17 and 19-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite with regard to the recitation of "recombinant FlaA or P37 protein"; are they the same protein? Claims 15-17, 22 and 23 are vague and indefinite in the recitation of "partial amino acid sequence"; what are the metes and bounds of partial? Claim 19 is vague and indefinite in the recitation of "said protein having the amino acid sequence of amino acids 1-319 of SEQ ID NO.:2"; is this the same sequence for both proteins FlaA and P37? Claim 27 is vague and indefinite in that it recites the amino acid sequence of claim 14 comprising and amino acid sequence, however

acid sequence of claim 15 or a complement thereof. In lines 1 and 2 there is

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insufficient antecedent basis for this limitation in claim 15; claim 15 recites that "protein having partial amino acid sequence of SEQ ID NO.:2". SEQ ID NO.:2 is an amino acid sequence only. Claim 29 recites the limitation "nucleic acid sequence of claim 15 or a complement thereof" in lines 1 and 2. There is insufficient antecedent basis for this limitation in claim 15; claim 15 recites that "protein having partial amino acid sequence of SEQ ID NO.:2". SEQ ID NO.:2 is an amino acid sequence only. Claim 30 is vague and indefinite in the recitation of "substantially"; what are the metes and bounds; how much of the amino acid sequence is necessary to determine substantially and what is "substantially antigenic"?

4. Claims 14-17 and 19-30 are rejected under 35 U.S.C. 102(a) as being anticipated by Ge et al, 1997 (J. Bacteriology; Infection and Immunity).

The claims (products and product by process) are directed to a recombinant FlaA protein or P37 protein; the protein has a defined amino acid sequence. The claims also set forth a fusion protein and that the transformed host in the recombinant process is *E. coli*.

Ge et al (J. Bacteriology, 1997) disclose a flagellin protein, FlaA, from *B. burgdorferi* having a molecular weight of 38 kD (abstract; p. 552). A lysate of *B. burgdorferi* showed strong reactivity to a protein of 38.0 kDa, which is consistent with the expression of FlaA in growing cells (abstract). Ge et al disclose the

homolog contains a typical signal sequence at its N terminus including a positively

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charged N-terminal domain, a central hydrophobic segment and a signal peptidase I cleavage site; after cleavage the mature protein has a molecular weight of 36 kD (p. 553). Western blot analysis of cell lysates of *B. burgdorferi* indicate that a single band of approximately 38.0 kD reacted with antiserum (figure 5; p. 555).

Ge et al (Infection and Immunity, 1997) disclose recombinant FlaA protein from *B. burgdorferi* (abstract). Ge et al disclose the cloning of *flaA* into expression vectors using *E. coli* and produces expression of the recombinant FlaA proteins (pp. 2992-2993). Ge et al disclose a fusion protein, FlaA protein and maltose binding protein or glutathione S-transferase (tables 1 and 2; pp 2992-2993). Ge et al disclose that the molecular weight is 38 kD (p. 2993). Figure 1 shows the amino acid sequence of the protein.

The prior art anticipates the claimed invention.

Applicant's arguments filed March 6, 2000 have been fully considered but they are not persuasive.

Applicants have asserted that Ge et al (II) states that "a putative flagellar outer sheath protein is not an immunodominant antigen associated with Lyme disease" and that it is not a good candidate for serodiagnosis of Lyme disease. However, the claims are directed to a product, the protein, which the prior art sets forth. Ge et al disclose that 2 Lyme disease patients reacted to recombinant FlaA and the native form (p. 2994, col. 2). In response to applicant's argument

noted that the features upon which applicant relies (i.e., immunodominant antigen)

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are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

5. Claims 14, 20 and 24 are rejected under 35 U.S.C. 102(a) as being anticipated by Fikrig et al (WO 97/42325).

Fikrig et al disclose a P37 protein to be used in the diagnosis of Lyme disease (abstract; pages 7, 10, 11 and 14-15). The prior art anticipates the claimed invention.

6. No claims are allowed.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(c). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within the shortened statutory period, then the period for filing a second reply shall be extended until the end of the **THREE-MONTH** shortened advisory action period.

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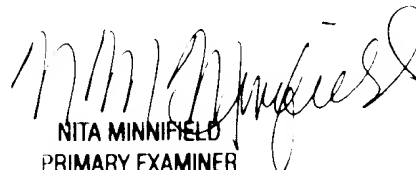
statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

N. M. Minnifield
May 18, 2000


NITA MINNIFIELD
PRIMARY EXAMINER